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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,832	11/16/2001	Adrian Sandler	DAS-1	5865

7590

04/29/2004

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 19-29 and 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413)

## DETAILED ACTION

Examiner acknowledges receipt of amendment filed 01/05/04. No claim was amended.

Examiner also acknowledges remarks made on the citation of art in the disclosure and acknowledges the prior art remarked as BG, BL and AO submitted on form PTO 1449.

Examiner acknowledges applicant's indication to cancel claims 19-29 and 42-44 when allowable subject matter is indicated in the claims under consideration.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 9-15, 30-33 and 36-38 rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,760,095).

White discloses a method and system for “effecting withdrawal from caffeine dependency” where the system comprises varying proportions of dosage units of caffeine and analgesic and where the method comprises administering a first dosage unit that has an equivalent daily caffeine intake, followed by a reduced level of caffeine, then gradually reducing the proportion of caffeine until individual no longer ingests caffeine and administration of placebo during the final stages of the method and system (abstract, column 1, line 56 to column 4 line 44). Disorder is generic term that includes caffeine dependency. White anticipates the claims.

### *Claim Rejections - 35 USC § 103*

3. Claims 1-18 and 30-41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dariani et al. (US 6,255,325).

Dariani discloses a treatment regimen attention deficit disorder where placebo and methylphenidate are alternated (abstract, columns 3 and 4 and examples 1 and 2). A predetermined time as recited in the instant claims is any time. Dariani starts out the treatment evaluation with a placebo (column 7, line 8) while in the instant case, the treatment starts with a pharmaceutical. However, there is no showing that administering a pharmaceutical before a placebo provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer a placebo to a patient in need thereof and then methylphenidate. One having ordinary skill in the art would have been motivated to experiment with administering methylphenidate and then the placebo with the expectation that the placebo would have no effect on the methylphenidate pharmaceutical.

Applicant argues that Dariani uses the placebo as one of two forms of comparison.

4. Applicant's arguments filed 01/05/04 have been fully considered but they are not persuasive.

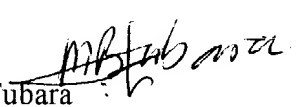
Although, Dariani uses the placebo as a comparison, the fact that the placebo has a reductive effect in ADHD activity is significant to contemplate use in treatment. Secondly, as a teaching reference, Brown (in "Placebo for Depression" Neuropsychopharmacology, vol. 10, no. 4, pp. 265-288) suggests initial administering a placebo followed by the administration of the specific medication and advocates that patients to be treated be told that the placebo contained no

drug. Although, Brown's teaching is for depression, ADHD and depression are neurological disorders. Besides, Brown is a specific teaching reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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